K013376

MAY 0 8 2002

510K Summary of Safety and Effectiveness

1. Sponsor Name

   Hemedex, Inc.
   222 Third Street, Suite T123
   Cambridge, MA 02142
   USA

2. Device Name

   QFlow™ 500 Perfusion Monitoring System

3. Identification of Predicate or Legally Marketed Device

   QFlow™ 500 is substantially equivalent to the following predicate devices:

   - Transonic Systems ALF 21 Advanced Laser Flowmeter cleared under K903633.
   - TSI LaserFlo™ Blood Perfusion Monitor cleared under K896515. (Vasamedics purchased TSI in 1990)
   - Vasomedics Laserflo Blood Perfusion Probes (K951832, K962700, K961368)

4. Device Description

   The QFlow™ 500 has application where real-time determination of any tissue perfusion is desired, whether it is for measurement or monitoring utilization. The system may be used in the Intensive Care Unit, Operating Room, Radiology Suite or in a standard patient care room. However, the system is not designed for use during patient transport.

   The QFlow™ 500 consists of a thermal diffusion probe and a monitor.

   The QFlow™ 500 Perfusion System Probe thermally interacts with tissue. It contains two thermistors embedded at the distal tip of the probe. It is available in a range of lengths from 60 cm to 120 cm and less than 1 mm in diameter. The probe contains an EEPROM for the storage of probe-specific calibration data, data on the cumulative time the probe has been in use, and a verification key to insure the origin of the probe. The probe connector physically connects the probe to the umbilical cord which connects to the monitor.

The QFlow™ 500 Monitor controls the thermistors in the Probe.

Perfusion data are displayed on the monitor. The current perfusion value, temperature and thermal conductivity are be displayed in numeric form. The data are also displayed in the form of a graph as a function of time.

The monitor is capable of storing data for up to 10 days. All of this stored data may be reviewed by the user at any time during this period. Printing of data is also an option from the monitor. There is also the capability of uploading data from the monitor to an external computer for further analysis.

5. Intended Use

The QFlow™ 500 is intended for extravascular monitoring of microcirculation blood flow in buried tissues. Examples of this application included (but are not limited to) 1) the monitoring of buried muscle or esophagus following free muscle transfer or esophageal reconstruction, 2) monitoring soft tissue microcirculation following reconstructive surgery, such as oral and facial reconstruction, 3) monitoring cerebral blood flow during and following neurosurgery for head trauma.

6. Comparison of Technological Characteristics

All of the devices are indicated to provide blood perfusion measurements in any perfused tissue where blood flow information is desired. However, the manner in which the measurements are made is different.

The QFlow™ 500 uses thermal energy dissipated in a thermistor to measure the thermal conductivity of the tissue and a real-time measurement of tissue perfusion. The predicate devices use laser light energy which is scattered by reflective components within the tissue and is reflected back via a receiving fiber optic probe. This provides a measurement of blood flow within the tissue.

The QFlow 500 is substantially equivalent to the predicate devices listed, which provide the same or similar functions, as well as design and technological characteristics. The intended use, statement of indications, and technological characteristics for the QFlow 500 support the concept of substantial equivalence.

7 Performance Testing

Bench testing, animal studies and biocompatibility testing was performed on the QFlow 500.

The QFlow™ 500 is tested for compliance with the following standards for electrical safety, thermal safety, electromagnetic compatibility, electromagnetic emissions and probe integrity:

IEC 60601-1 (1988) 2nd Edition, + A1: 1991 + A2: 1995 Medical Electrical Equipment – General Requirements for Safety

IEC60601-1-2: 1993 Medical Electrical Equipment – Collateral Standard Electromagnetic Compatibility

EN 55011 Limits and Methods of Measurement of Radio Disturbance characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment.

UL2601, UL standard for Safety, Medical Electrical Equipment, Part 1: General Requirements for Safety, First Edition

ISO 10555 Sterile, single-use intravascular catheters Part 1: General Requirements

ISO 10993: 1997 Biological evaluation of medical devices
Part 1: Guidance on selection of tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 8 2002

Hemedex, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
Hopkinton, MA 01748

Re: K013376
Trade Name: QFlow 500 Perfusion Monitoring System
Regulation Number: 21 CFR 870.2100
Regulation Name: Blood Flow Monitor
Regulatory Class: Class II (two)
Product Code: DPW
Dated: February 11, 2002
Received: February 12, 2002

Dear Ms. Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013376

Device Name: QFlow 500 Perfusion Monitoring System

Indications For Use:

The QFlow™ 500 is intended for extravascular monitoring of microcirculation blood flow in buried tissues. Example of this application included (but are not limited to) 1) the monitoring of buried muscle or esophagus following free muscle transfer or esophageal reconstruction, 2) monitoring soft tissue microcirculation following reconstructive surgery, such as oral and facial reconstruction, 3) monitoring cerebral blood flow during and following neurosurgery for head trauma.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013376